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DETAILED ACTION

Claims 18, 21-25, 28, 39-58 are pending. Claims 18, 21-25 and 28 are under consideration. Claims 39-58 remain withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2009 has been entered.

Objections/Rejections Withdrawn

- 2. Claim Objections Claim 18 objected to because of the following informalities, specifically for reciting the phrase "Figure 1A" has been obviated by removal of this recitation and insertion of the actual figure.
- 3. **Drawings** The drawings objected to as failing to comply with 37 CFR 1.84(p)(5) because they included reference character(s) not mentioned in the description has been obviated by amendment of the Brief Description of the Drawings and the Figures .
- Figure 1A recites the descriptors of "TagO" and "DltABCD" which are not described in the Brief Description of Figure 1A.
- Additionally, [031] refers to "highlighted in gray boxes" (no gray boxes are shown),
- [034] refers to "gray bars" (which are shown as white or black bars).
- [038] refers to "gray triangles" which are only shown in the LL-37 figure, while the other two images also have Δ's that are not gray.

Objections/Rejections Maintained/ Response to Arguments

1. Applicant's arguments filed November 4, 2009 have been fully considered but they are not persuasive.

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Maintained, Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 3. **Maintained**, Claims 18, 21-25 and 28 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 7-10 of U.S. Patent No. 7,169,903 is traversed on the grounds that the instantly claimed antibodies "specifically bind to ribitol phosphate wall teichoic acid (WTA) of figure 1A of S. aureus" and the allowed claims being to PepG and lipoteichoic acid (LTA) and the pending claims have been limited to antibodies that encompass different subject matter and "would not significantly cross-react with peptidoglycan or lipoteichoic acid (LTA).
- 4. Applicant's traversal has been considered and not found convincing because monoclonal antibodies specifically bind to the antigen to which they were stimulated, and ribitol teichoic acid and lipoteichoic acid have shared antigens in common to which the monoclonal antibodies would specifically bind. The claims do not recite the phrase "would not significantly cross-react with peptidoglycan or lipoteichoic acid" as asserted by Applicant; the traversal is not commensurate in scope with the instantly pending claims.
- 5. US Pat. 7,169,903, claims 7-10 include antibodies directed to lipoteichoic acid that include monoclonal antibodies directed to lipoteichoic acid components that encompass S.

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aureus WTA which have a shared common WTA structure such as "D-Alanine esters or GlcNAc" (N-acetylglucosamine) modification and cross react with WTA from other staphylococcal species.

6. Though the scope of the allowed claims is not identical to the instant claims, the allowed claims are directed to a genus of compositions that comprise antibodies of the instant claims, the instant claims being a species of invention encompassed by the allowed genus. (structural comparison provided below (Lipoteichonsure= Lipoteichoic Acid; Wandteichonsaure=Wall teichoic Acid), wherein the left half of the two molecules share conserved antigenic domains to which the composition of allowed antibodies would bind in both WTA and LTA of a ribitol wall teichoic acid and a ribitol containing lipoteichoic acids.

7,169,903 Allowed claim 6. The composition of claim 1 or 2, further comprising an additional MAb, or a antigen-binding portion thereof, that specifically binds to lipoteichoic acid (LTA) of Grampositive bacteria.

Lipoteichonsäure

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US Pat. 7,169,903 [0003] "The claims include monoclonal antibodies directed to GleNAc (Nacetylglucosamine) modification and cross react with WTA from other staphylococcal species "[0041] The term "wall teichoic acid" (WTA), as used herein, includes complex surface-exposed polymers covalently linked to the peptidoglycan in staphylococcal cell walls. WTA also includes soluble whole WTA or fragments thereof. In one embodiment, WTA may be produced synthetically. In another embodiment, WTA may be isolated from staphylococci such as, but not limited to, S. aureus. The cell walls of Gram negative bacteria are made up of a unique outer membrane of two opposing phospholipid-protein leaflets, with an ordinary phospholipid in the inner leaflet but the extremely toxic lipopolysaccharide in the outer leaflet. The cell walls of Gram positive bacteria seem much simpler in comparison, containing two major components, peptidoglycan and teichoic acids plus additional carbohydrates and proteins depending on the species. "The obviousness type double patenting rejection is maintained for reasons of record and responses set forth herein.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. **Maintained**, The rejection of claims 18, 21-25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Gotz and Peschel (common inventor, DE19912706) et al in light of English translation, in view of Fischer (reference of record, US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999) is traversed on the grounds that:

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acid;

a. The claimed antibody composition must be specific for ribitol phosphate wall teichoic acid of S. aureus;

- b. The composition must comprise a pharmaceutically acceptable carrier
- c. And must contain an amount of antibodies effective to alleviate or block nasal colonization or infection by S. aureus upon administration.
- d. States the active agents of Gotz et al are not antibodies or antiserum and Gotz does not teach the functional limitations of the instant claims.
- 9. It is the position of the examiner that Gotz et al was not applied against the claims under 35 USC 102, but under 35 USC 103 in combination with Fischer et al and Patti et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
- e. Gotz et al does teach antiserums (see Gotz, DE19912706, col. 6, lines 28-30, and English machine translation) that are specific to recognize alanine-substituted and non-substituted Teichoic acids of S. aureus to include the wall teichoic acid of S. aureus Sa113 (see Figure 1,Gotz), the wall teichoic acid of S. aureus Sa113 being a ribitol phosphate wall teichoic
 - Fig. 1 schematic structure of Lipo and Wandteichonsäuren. With the Wandteichonsäuren of S. aureus first three Glycerolphosphateinheiten, followed of approx. follow after the connecting unit. 40 Ribitolphosphateinheiten. With the Wandteichonsäuren of S. xylosus Glycerol and Ribitolphosphateinheiten in the same proportion are present. MurNAc: N- Acetylmuraminsäure; GlcNAc: N-acetylglucosamine.

f. Gotz et al does teach pharmaceutical carriers in combination of pharmaceutical compositions (see Gotz, DE19912706 and English machine translation claim 27);

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g. Gotz et al teach the importance of formulating pharmaceutical compositions against WTA, and methods of screening for active ingredients that reduce growth and/or survival rates of the microorganisms to include reduction or prevention of biofilm formation. Gotz et al teach the active ingredient is preferably a protein or peptide.

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10. Gotz et al was applied against the claims for teaching the importance of blocking the binding of S. aureus WTA to host animal receptors, for teaching anti-ribitol teichoic acid antibodies induced to the WTA of Staphylococcus aureus strain Sa113, the antibodies recognizing the ribitol teichoic acid antigens to include the D-alanine epitope contained in the

ribitol WTA.

Goetz Figure 1 "Wandteichonsaure"), the chemical structure

While Gotz et al teach the active agent to preferably be a peptide or a protein, the examiner agrees that Gotz et al does not describe the anti-ribitol WTA antibodies to be the active agent, and the antibodies are polyclonal antibodies rather than the claimed monoclonal antibodies.

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11. Applicant asserts that Fischer et al does not add anything to Gotz et al.

- 12. Contrary to Applicant's position with respect to Fischer et al, the examiner appreciates the fact that Fischer et al teach how the make and use polyclonal, monoclonal, chimeric, human and humanized antibodies for anti-teichoic antibodies (see col. 22, lines 48-52, col. 5, lines 32-40) and teach Staphylococcus aureus produces ribitol teichoic acids (see col. 5, lines 32-35;;see col. 22, lines 30-35 and 48-52), abstract and col. 2, line 2), wherein anti-teichoic acid antibodies provide for increased opsonization and phagocytosis of S. aureus (see col. 22, lines 30-35 and 48-52).
- 13. Fischer et al clearly adds to the knowledge of one of ordinary skill in the art with respect to peptide and protein active agents that will specifically bind to Staphylococcus aureus teichoic acids, wherein increased opsonization and phagocytosis of S. aureus will block colonization of S. aureus. Gotz et al teach specific ribitol teichoic acid antibodies were known and could be readily made by any one of the methods of Fischer et al and in light of the guidance and teaching of Fischer et al.
- 14. Applicant asserts that Patti et al neither teach nor suggest antibodies which specifically bind to the ribitol teichoic acid of S. aureus as set forth in the instant claims.
- 15. It is the position of the examiner that Patti et al. teach pharmaceutical compositions (see col. 8, lines 20-23; col. 39, line 34) that comprise antibodies (see col. 39, lines 32-35), the antibodies including anti-teichoic acid antibodies (see col. 39, line 35 "as described above) specific for ribitol teichoic acid (see col. 22, lines 48-52 and lines 36-47 "opsonic antibodies")

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together with a pharmaceutically acceptable carrier (see col. 39, lines 36-37) in a therapeutically effective amount (see col. 40, lines 14-15) administrable by an intranasal route (nasogastric (col. 28, line 66) or nasopharyngeal (col. 44, line 15) for the purpose of passive immunization (see col. 9, lines 1-2) and blocking colonization of S. aureus in the nose of a subject (col. 5, line 39).

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Gotz et al in combination with Fischer and Patti obviate the instantly claimed invention because Patti et al teach anti-ribitol and anti-glycerol teichoic acid antibodies provide for increased opsonization and phagocytosis of Staphylococcus aureus and Fischer et al teaches ribitol and glycerol teichoic acids are major antigens in the cell of gram positive/Staphylococcal pathogens to include Staphylococcus aureus and teach the production of monoclonal antibodies are highly specific to the antigen to which they bind and are not dependent on animals for production and the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining monoclonal anti-ribitol teichoic acid antibody compositions directed to the S. aureus cell wall antigen of Gotz et al, because Patti et al teaches that through using ribitol phosphate linked to peptidoglycan, the teichoic acids are antigenic and anti-teichoic acid antibodies are produced (see col. 22, lines 48-52) and Fischer et al teach and provide motivation for the production of monoclonal antibodies, and recombinant antibodies and fragments specific to ribitol teichoic acid, the anti-ribitol teichoic acid antibodies being means that provides for the generation of vaccines and other therapeutics (see Fischer abstract).

Gotz et al in view Fischer and Patti obviated the instantly claimed invention as now claimed.

16. Gotz et al teach and show the chemical structure of the ribitol teichoic acid (see De 19912706, figure 1, Wandteichonsaure) for Staphylococcus aureus strain Sa113 (same strain as the instant Application, see De 19912706 col. 7, line 45) and antibodies directed thereto (see De 19912706 col. 5, line 62 "spezifischen Antiseren", col. 6,lines 28-30 and lines 17-32, col. 6, lines

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56-58 and English machine translation). Goetz et al teach antibodies in antiserum ("antiserums, which recognize specific alanine-substituted... Teichonsauren") that specifically bind to the ribitol teichoic acid of Staphylococcus aureus strain Sa113:

Goetz et al teach active agents that reduce or inhibit Gram Positive bacterial adherence/infection and biofilm formation (see at least claims 19-26), formulation of compositions for administration, suggests pharmaceutical compositions and polyclonal antibodies directed to the ribitol wall teichoic acid of Staphylococcus aureus but differs from the instantly claimed invention by failing to show the antibodies in the compositions to be monoclonal antibody compositions formulated as pharmaceutical compositions.

Fischer et al teach the importance of producing polyclonal, monoclonal, chimeric, human and humanized antibodies to ribitol phosphate teichoic acids (see col. 5, lines 32-35) in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52, col. 5, lines 32-40) associated with Staphylococcal aureus antigens (aureus (see col. 22, lines 30-35 and 48-52), abstract and col. 2, line 2) to increase the opsonization and phagocytosis of S. aureus (see col. 22, lines 30-35 and 48-52).

Patti et al teach the production of antibodies to glycerol or ribitol phosphate in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52) associated with staphylococcal antigens (abstract) to increase the opsonization and phagocytosis of S. aureus and to serve as pharmaceutical compositions in treating Staphylococcal infections.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Gotz et al to comprise monoclonal antibodies as taught by Fischer et al and to formulate them into pharmaceutical compositions as taught by Patti et al because Patti et al teach anti-ribitol and anti-glycerol teichoic acid antibodies provide for increased opsonization and phagocytosis of Staphylococcus aureus and Fischer et al teaches ribitol and glycerol teichoic acids are major antigens in the cell was of gram positive/Staphylococcal pathogens to include Staphylococcus aureus and monoclonal antibodies are highly specific to the antigen to which they bind and are not dependent on animals for production.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining monoclonal anti-ribitol teichoic acid antibody compositions directed to the S. aureus cell wall antigen of Gotz et al, because Patti et al teaches that through using ribitol phosphate linked to peptidoglycan, the teichoic acids are antigenic and antiteichoic acid antibodies are produced (see col. 22, lines 48-52) and Fischer et al teach and provide motivation for the production of monoclonal antibodies, and recombinant antibodies and fragments specific to ribitol teichoic acid, the anti-ribitol teichoic acid antibodies being means that provides for the generation of vaccines and other therapeutics (see Fischer abstract). Gotz et al in view Fischer and Patti obviated the instantly claimed invention as now claimed.

In re Erlich 1988 teaches that it is obvious to make a monoclonal antibody to an antigen to which a polyclonal antibody is known.

Additionally, KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method, and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. KSR International Co. v. Teleflex

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Inc., 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar element according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to use monoclonal antibodies for formulation of compositions to a specific ribitol teichoic acid, the guidance and teaching of the references provide a solution to providing a ready source of specific antibodies that maintain their specific binding characteristics, and reduces the dependence upon immunization of animals to produce an antibody containing antisera that would vary upon the immune systems of different animals. Thus, it would be obvious to apply a known technique (monoclonal antibody production) to a known product (generation of antibody containing antiserum specific to ribitol wall teichoic acid) to be used in a known method (generation and formulation of monoclonal antibody compositions) that is ready for improvement of having a ready sources of ribitol specific antibodies for the formulation of pharmaceutical compositions to assist in the treatment of Staphylococcal infections.

Amendments/Claim amendments/New Grounds of Objection/Rejection Specification

17. The amendment filed June 30, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: [031] has been amended to more clearly describe Figure 1, but Figure 1 only shows TagO and DltABCD and not a genus of genes or operons encompassed by the recitation of the phrase "such as TagO and DltABCD". The phrase "such as" is not support by Figure 1 and does not evidence original descriptive support in Figure 1A or in the original Brief Description of Drawing Figure 1A and therefore is New Matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

18. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly

labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

- 19. Figure 4 continued was submitted in Amended form, but a Mark-up copy did not accompany the amended figure.
- 20. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

21. Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 28 recites the composition of claim 18 together with a pharmaceutically acceptable carrier. In light of the amendment of claim 18 to now require the

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presence of a pharmaceutically acceptable carrier, the composition of claim 28 is no longer further limiting of the composition of claim 18.

22. Claim 28 is objected to because of the following informalities: Claim 28 recites the phrase: "A passive immunotherapy comprising"; a transitional phrase is missing, specifically the term ----composition--- following the term "immunotherapy". Claim 28 is a composition claim and should be clearly set forth as such. If claim 28 is not amended to clearly define the claim as a composition this objection will be maintained; if claim 28 is amended to a non-elected category of invention, the claim will be withdrawn from consideration as the claim has always been examined as a composition claim based upon the recited components following the term "comprising" which are composition components. Appropriate correction is required.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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24. Claim 18 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Aasjord et al (1985). Aasjord et al disclose a composition that comprises a monoclonal antibody specific to Satphylococcus aureus β-N-acetylglucosaminyl ribitol teichoic acid (see page 246, col. 1, p. 1, bottom of paragraph and col. 1, p.5, "Monospecificity was checked by testing against other staphylococcal antigensB-RTA"; and page 247, col. 2, p. 1 "Monoclonal antibodies to other staphylococcal antigens such as ... B-RTA"), (monoclonal antibody C6 and C7, page 247, Figure 1 and Results) which specifically bind to the glycerol-phosphate backbone of LTA (see page 248, co... 2, p. 3, last sentence bridging to page 249) together with a pharmaceutical carrier (see page 246, col. 2, p. 1 "0.01M phosphate buffered saline (PBS), pH 7.2").

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While Aasjord et al does not discuss the function limitations of the instant claims, the monoclonal antibody specificity is the same or equivalent as now claimed, and the monoclonal antibody compositions of Aasjord et al comprise a pharmaceutically acceptable carrier.

- 1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594
- 2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art=s functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

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Conclusion

25. This is a non-final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/ Examiner, Art Unit 1645 January 13, 2009

/Robert B Mondesi/ Supervisory Patent Examiner, Art Unit 1645